Research & Development Committee

STANDARD OPERATING PROCEDURES

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REVISIONS

Revisions from April 24, 2019 to March 24, 2021:

- Removed requirement that studies under the purview of the VA CIRB submit approved CR packet to R&D as a notification. R&D will be made aware of CRs via VA CIRB minutes and has access to all approval documents via SharePoint and IRBNet.

Revisions from June 27, 2018 to April 24, 2019:

- Updates related to the issuance of VHA Directive 1200.01 dated January 24, 2019.

- Added provisions for designated review.

- Added provisions for R&DC contingent approval pending subcommittee approval.

- Clarified R&DC review procedures based on oversight by subcommittees, external IRBs, and R&DC as the only oversight committee

- Added R&DC oversight of non-Veterans as research participants.

Revisions from June 28, 2017 to June 27, 2018:

- Updated Section 5.2.3 Review of VA CIRB Studies: Removed the requirement to submit amendment approvals a notifications to R&DC; and clarified RCO reporting requirements to CIRB.

Revisions from July 27, 2016 to June 28, 2017:

- Added: 5.2.5 Systemic Deficiencies, per VHA Handbook 1058.01, Research Compliance Reporting Requirements, June 15, 2015.

- 5.2 Review of Subcommittee Research/Items: Clarified that PI changes will not go to R&DC convened meeting for review. PI changes will be approved by IRB and included on the sub- committee approval list provided to R&D.

- Added Section: 9.6 VA Central Institutional Review Board (NCI CIRB).

- Clarified trainee research, per VHA Directive 1200.02 and VHA Handbook 1200.05, under section: *10. INVESTIGATOR RESPONSIBILITIES*

Revision the June 22, 2016 to the July 27, 2016 version:

- Revised local continuing review requirements for VA CIRB studies. Submission of a local CR packet to R&D is no longer required. VA CIRB studies will submit CIRB CR packet and approval documents to R&D as a notification.

1. PURPOSE AND AUTHORITY

The Research & Development Committee (R&DC) at the Durham VA Health Care System (DVAHCS) is responsible, through the Chief of Staff (COS) to the Medical Facility Director (MFD), for oversight of the research program and for maintaining high standards throughout the R&D Program. The standards include assuring the scientific and ethical quality of research and development projects, the protection of human subjects in research, the use and welfare of laboratory animals, the safety of personnel engaged in research, the safety and security of VHA research laboratories, and the security of research data, and resources.

The MFD is the Institutional Official responsible for Federal Wide Assurance, (FWA) and the Animal Welfare Assurance (OLAW). The MFD delegates the authority to administer the R&D program to the Associate Chief of Staff for Research & Development (ACOS/R&D), who reports to the MFD through the COS. The R&DC is assisted by the ACOS/R&D and the Administrative Officer (AO) for R&D in carrying out its duties.

The Research Compliance Officer(s) (RCO) advise the R&DC on regulatory affairs and federal, VHA, and accreditation standards and has delegated authority for evaluation and monitoring of research activities at the level of individual investigator and research personnel. The R&DC advises the MFD on professional and administrative procedures involving the R&D Program.

Research in which the DVAHCS is to be engaged may not be undertaken without review and written approval of all applicable subcommittees of the R&DC. The investigator must not initiate a research project until notified in writing by the ACOS/R&D that the project has been approved by all relevant committees, subcommittees, or other entities.

2. DEFINITIONS

Internal IRB(s) – An IRB that is constituted *on-site* at a VA facility and the VHA Central IRB.

External IRB(s) – Any IRB that is not an internal IRB [e.g., a National Cancer Institute IRB(s)].

Internal Committee or Subcommittee – Any research committee that is constituted *on-site* at a VA facility.

External Committee – Any research committee that is not constituted on-site at a VA facility. Note that the VHA Central IRB, while an internal IRB, is an external committee.

Data Repository – A database or collection of databases that have been created or organized to facilitate the conduct of multiple research protocols, including future protocols not yet envisioned. It may also have been created for administrative and

clinical purposes. The terms “data repository” and “data warehouse” have the same meaning.

Research – A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Research Data Repository – A data repository created from data obtained either to conduct a research protocol(s) or gathered in the course of conducting a research protocol and is maintained after the completion of the research protocol. The protocol may be a primary research project designed to prove or disprove a specific hypothesis or it may be a protocol specifically designed to collect data (either a one-time-only collection of data or an ongoing collection) that will be placed in a research data repository for future use.

Systemic Deficiency – A systemic deficiency is a fundamental, underlying problem that jeopardizes the effectiveness of the facility’s research protection system(s).

VA Research – Research that is conducted by VA investigators (serving on compensated, work without compensation (WOC), or Intergovernmental Personnel Agreements (IPA) appointments) while on VA time, utilizing VA resources (e.g., equipment), or on VA property including space leased to, or used by VA. The research may be funded by VA, by other sponsors, or be unfunded.

VA Data / VA Information – VA data or VA information owned or in possession of VA or any entity acting for, or on behalf of VA.

VA Sensitive Information – All VA data, on any storage media or in any form or format, which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information. The term includes information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, records about individuals requiring protection under various confidentiality provisions such as the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, and information that can be withheld under the Freedom of Information Act (FOIA).

VA Protected Information – VA sensitive information, Privacy Act Information (PAI), Protected Health Information (PHI), or other VA information that has not been deliberately classified as public information for public distribution. VA information that VA would have to release under the FOIA is not VA protected information. All VA protected information needs to be classified as one of the following: VA Proprietary, VA Restricted, or VA Highly Restricted.

3. RESPONSIBILITIES OF THE MEDICAL FACILITY DIRECTOR (MFD)

The MFD is responsible for the R&D program and is assisted by the R&DC.

The Durham VAHCS MFD:

- Serves as the Institutional Official (IO) responsible for all aspects of the research program and signs all assurances.

- Ensures that research in which DVAHCS is engaged is approved by the R&DC and appropriate subcommittee(s).

- Ensures there are adequate resources and administrative support, including personnel, space, and equipment, for the R&DC and its subcommittees to fulfill their responsibilities.

- Suspends or terminates research that has been approved by the R&DC when there are substantiated concerns about the conduct of the research.

- Appoints R&DC members (and subcommittee members) in writing.

4. RESPONSIBILITIES OF THE ASSOCIATE CHIEF OF STAFF RESEARCH AND DEVELOPMENT (ACOS/R&D)

The Durham VAHCS ACOS/R&D:

- Notifies investigators when a research project can be initiated. This notification occurs only after the research project has been approved by all applicable R&DC subcommittees and after the R&D subcommittees' notifications of approvals have been approved by the R&DC.

- Functions as Executive Secretary of the R&DC and provides administrative support to the R&DC.

- Provides support to the R&DC for an annual quality assurance review of subcommittees, external committees, and other aspects of the research program.

- Ensures that all minutes of the R&DC and its subcommittees are sent to the MFD and COS for review.

5. RESPONSIBILITIES OF THE RESEARCH AND DEVELOPMENT COMMITTEE

The Durham VAHCS R&DC:

- Assists the MFD in fulfilling responsibilities for the facility's research program. The R&DC is responsible for ensuring the effective operation of the research program and making appropriate recommendations, including space and resource needs, to the MFD.

- Reviewing research proposals, ensuring that all research is consistent with the VA mission and that the research complies with statutory and regulatory requirements.

- Ensuring that the research engaged in by the facility is of high scientific quality, has adequate protections for human subjects, animal subjects, and research personnel, and has adequate protections for the safety and security of VA data and laboratory space.

- Reviewing and evaluating all R&D subcommittees and research-related external committees. A summary of these reviews and evaluations must be sent to the MFD annually.

- Ensuring that the appropriate IRB agreements are in place as required by VHA Directive 1200.05(2) and VHA Handbook 1058.03 prior to using an external IRB or a non-VA IRB serving as the single IRB for a multi-site study.

- Ensuring that classified research is not conducted as VA research.

- Establishing a local conflict of interest review process to ensure that potential conflicts of interest are reviewed, reported, and managed per government ethics rules.

- Ensuring that ISSO and PO review is complete before a study is given final approval.

- Reviewing the operations and functions of all research-related committees and subcommittees.

In fulfilling its responsibilities of ensuring the effective oversight of the research program and making appropriate recommendations to the MFD the R&DC needs to rely on a variety of information sources including:

- Quality assurance activities, reporting to the committee through the ACOS/R&D, AO/R&D or other research staff members, subcommittee reports, facility reports or activities, and other sources when relevant.

- Review of R&DC subcommittee and other committee operations must be conducted as an ongoing function of the R&DC. The review must be conducted at least annually and must be accomplished in part by (1) reviewing the minutes of each subcommittee that reviews VA research protocols, (2) close communication with the subcommittees and (3) through quality assurance and quality improvement activities. Reviews must be sent to the MFD annually.

Review of **subcommittee** activities include:

- Annual reviews of the Research Safety and Security Program (including planned training, compliance, security issues, etc.);

- The Animal Care and Use Program (including inspection reports, IACUC composition, IACUC arrangements, space, support staff, training, quality improvement activities, compliance issues, and goals for the next year).

- The Human Research Protection Program (including IRB composition or IRB arrangements, credentialing and training status report, space, support staff, quality improvement activities, compliance issues, and goals for the next year).

Review of **external committee** activities include:

- Facility-specific aspects of relationships with external committees such as inter-committee communication and processes.

- Ensuring the details and the obligations of the Memorandum of Understanding (MOU) are being met.

5A. Review of Research

The R&DC has the authority to review research and approve it, require modifications to obtain approval, or disapprove the research. This review must promote:

- Maintenance of high standards of protocol review, and relevance to the mission of VA.

- Protection of human subjects (including privacy and confidentiality), and the implementation of adequate safety measures for research subjects and personnel.

- Welfare and appropriate use of animals in research.

- Safety of personnel engaged in research.

- Security of research laboratories where hazardous agents are stored or utilized.

- Security of VA data and VA sensitive information.

If a research protocol requires review by a facility's non-research entities, such as the Radiation Safety Committee, this review may be conducted at any time, but the research may not be initiated until the non-research entity has approved the project, and the project has been approved by all applicable R&DC subcommittees, and the investigator has been notified in writing by the research office.

The IRB, Subcommittee for Research Safety/Institutional Biosafety Committee (SRS/IBC), IACUC and other such entities must notify the R&DC of final project approvals via a written communication signed by a voting committee member for the committee. For Durham VAHCS subcommittees, a single memorandum that lists the study title and unique study number for all studies receiving final approval before or during the last convened subcommittee meeting will be provided to R&DC. For external committees such as the VA CIRB studies, the R&DC must have the signed final VA CIRB approval letter. The R&DC must notify the ACOS/R&D of project approvals via a written communication signed by a voting R&DC member for the committee. Once R&DC approval has been given, the research becomes VA approved research.

5B. R&DC Designated Review

A designated review process may be used by the R&DC. A designated reviewer is an R&DC Chair/Co-Chair or a voting member assigned by the Chair/Co-Chair. A designated review process can be used for:

- Minor changes to a protocol reviewed by R&DC after a convened meeting R&DC review.
- Final approval of protocols that have received contingent approval by a subcommittee that do not require major changes to the protocol since the R&DC conducted its review.
- Final approval contingent upon completion of ISSO and PO review.
- Exempt human subject protocols and protocols approved by expedited review by the IRB.
- Single patient expanded access protocols as approved by the IRB.
- Protocols that do not involve (1) human subjects, (2) BSL-3 or higher containment, (3) use of select agents or non-exempt quantities of toxins, (4) USDA-regulated animal species, or (5) animal research that includes more than momentary pain or distress.

5C. R&DC Review of Research as the Only Oversight Committee

The R&DC will conduct initial review, continuing review, and review of amendments for research projects that are not otherwise reviewed by the IRB, IACUC, or SRS/IBC. This includes protocols that meet exemption criteria by the IRB. A specific approval period not to exceed 1 year must be set and is based on risk assessment. The R&DC may approve, approve with contingencies, table/defer, or disapprove a research project, program or center. This review includes assessment of research activities:

- With the research progress made in the last year

- Any issues that might impact progress such as compliance, unanticipated problems, budgetary changes, space or personnel issues.

- Whether the basis for IRB exemption still exists (if applicable)

- If the project's scientific quality, ethical appropriateness and safety of the research continues to meet the criteria forapproval.

5D. R&DC Review of Research Overseen by a Subcommittee

The Durham VAHCS will not routinely provide protocol reviews for protocols reviewed by one of its three subcommittees. The R&DC must receive notice from the subcommittees that the protocol has been approved and a summary of the research to be conducted.

For research overseen by a subcommittee the R&DC may:

- Approve protocols contingent on the protocol being approved by one or more of the DVAHCS subcommittees. A designated review process may be used if there are no major changes made by a subcommittee(s). Final approval may only be granted by the R&DC after it receives documentation of the subcommittee granting final approval and final R&DC approval must be reported at the next convened R&DC meeting and reported in the minutes.

- The R&DC may disapprove a study even if approved by all subcommittees.

- The R&DC will not be required to approve continuing reviews and amendments. Documentation regarding continuing review an amendments overseen by a subcommittee will appear in that subcommittee's minutes.

5E. R&DC Review of Research Overseen by External IRBs

For research overseen by an external IRB the R&DC:

- Will conduct an initial review of studies overseen by an external IRB. Specifically, the R&DC must determine that the research supports the VA mission, is scientifically meritorious, and ensures data security.

- Will vote to approve, approve with contingencies, table/defer, or disapprove the research in a convened meeting unless the research can be approved by designated review.

- Does not approve continuing reviews or amendments to research overseen by an external IRB. Documentation regarding continuing review and amendments overseen by a subcommittee will appear in that subcommittee's minutes.

- The R&DC may disapprove a study that was approved by an external IRB.

5F. Review of VA CIRB Studies

Per the VA CIRB and Durham VAHCS Memorandum of Understanding (MOU), the R&DC provides a local review of CIRB-approved studies. This review of the research assesses local impact of the research and ensures that the research has adequate resources. The R&DC must approve a CIRB study before the research may be initiated.

Initial Review. The R&DC must conduct an initial review of studies approved by the CIRB. R&DC must approve the research before any research procedures or activities can be initiated at the Durham VAHCS. The complete and approved Principal Investigator/Study Chair (PI/SC) application or Local Site Investigator (LSI) application and CIRB approval documentation is submitted to R&D Committee along with the *Application for Initial Review of Research—VA CIRB Project* form. If the Durham VAHCS investigator is serving as the PI/SC and as the LSI, the complete and approved PI/SC application and LSI application must be submitted to R&DC. If the DVAHCS investigator is only serving as the LSI, only the complete LSI application will be submitted to R&DC. If any local service support is required (i.e., Pharmacy, Pathology), a letter of support from the service(s) must be included in the initial review submission to R&DC.

Continuing Review. . The R&DC will not perform a local continuing review of research projects for which the VA CIRB is the IRB of record. The RD&C will be made aware of continuing review approvals via VA CIRB minutes and will retain access to approval documents via SharePoint and IRBNet.

Amendments and Other Submissions. CIRB approved amendments, notifications, modifications, or updates to studies under the purview of VA CIRB do not require review by R&DC, unless requested by the RCO, VA CIRB, or ACOS/R&D. If the modification includes personnel being added to a VA CIRB study, an updated staff listing will be submitted to the DVAHCS Research Office. Credentialing, applicable privileging, Research Scope of Practice, and proof of ethical principles training in human subject research (i.e., CITI training) must also be received by the DVAHCS Research Office for that individual. All VA CIRB approved amendments, notifications, modifications, updates, and all other CIRB correspondence will be stored and maintained in the investigator study files. The local site liaison is notified by VA CIRB when approved study documents are available on SharePoint site. Copies of all approved documents will be stored in the Research Office in the electronic protocol file and accessible to R&DC, local RCO(s), and ACOS/R&D.

No changes to the protocol should be implemented locally until the modifications receive VA CIRB approval. Modifications may only be implemented locally without prior VA CIRB approval to eliminate apparent immediate hazards to the human subjects. If changes are made locally without prior VA CIRB approval, the VA CIRB must be immediately notified, in addition to the R&DC.

After the VA CIRB has approved study closure at the DVAHCS, the LSI will submit the complete and approved VA CIRB study closure application to R&DC. The LSI will be provided with written notification when R&DC approves the study closure.

The R&D Committee will review and approve the VA CIRB minutes at which initial review, continuing reviews, notifications, and modifications were discussed and approved.

Reporting to the VA CIRB. The PI/SC or LSI must promptly inform VA CIRB of any complaints from participants or others, serious adverse events, unanticipated problems, suspensions or terminations of research, and/or apparent serious or continuing noncompliance.

Research compliance reporting requirements will be met according to VHA Handbook 1058.01 and the signed MOU between VA CIRB, DVAHCS and the NPC. VA CIRB will be notified of any local action mandated by the R&D Committee, local subcommittees, RCO(s), or ACOS/R&D.

Routine RCO audits that have no substantive findings will be submitted by the RCO to the study team and to the VA CIRB via the VA CIRB administrator. Apparent serious noncompliance will submit the report directly to VA CIRB within 5 business days of the finding. All routine audits of VA CIRB approved projects conducted by the facility RCOs will be reported to R&DC Committee via monthly spreadsheets used to report all facility auditing results and progress.

The R&D Committee will review and approve the VA CIRB minutes at which all compliance events and other reportable events were reviewed and discussed.

5G. R&DC Review of Collaborative Research

For collaborative research projects, each institution engaged in research is responsible for the research activities occurring at its site(s). The R&DC must ensure that it is approving only those research activities that occur at the Durham VAHCS. The Durham VAHCS R&DC (and its subcommittees) may require that Durham VAHCS-specific protocol be developed and submitted for review.

5H. R&DC Review of Research for Data Repositories

R&DC will review the creation and operation of research data repositories and will review individual protocols that will use data from a research or non-research data repository in

accordance with VHA Handbook 1200.12. A research data repository can be created only after a research repository protocol and corresponding standard operating procedures are developed and approved by the IRB (if human research is involved) and the R&D Committee. If the research data repository or use of data from a data repository involves human subjects, the repository and/or protocol will first be reviewed by the IRB, then the R&DC.

5I. R&DC Review of PI Changes

The R&DC will not routinely review all requests to transfer/change Principal Investigator responsibilities to another Principal Investigator unless the R&DC is the only oversight committee. R&DC will be notified of approval for PI change through minutes and subcommittee approvals.

5J. R&DC Review of Non-Veteran Participation as Research Subjects

Non-veteran enrollment in VA research that does or could involve VA outpatient or VA hospital treatment may only occur when there are insufficient Veteran patients suitable for the study. Non-Veterans may not be entered into VA studies because a non-Veteran population is more easily accessible to the investigator.

The R&DC must review the justification and *specifically approve* the enrollment of non-Veterans in the study. All VA regulations and policies related to Veterans as research subjects apply to non-Veterans entered into VA research studies.

Non-Veterans may be recruited for studies that generally benefit Veterans but would not include Veterans as subjects. Examples include surveys of VA providers or other employees and studies involving Veteran family members and/or caregivers.

5K. Review of Serious or Continuing Noncompliance, Unanticipated Problems, or other Reportable Issues from any Subcommittee

Incidents that require reporting to ORO or any governing body will be reported to the R&DC monthly at regularly scheduled convened meetings. Status updates on each issue will be reported monthly until the incident is closed to the satisfaction of the oversight office.

Any subcommittee of the R&DC may send issues to the R&DC for review, including but not limited to compliance issues, unanticipated problems, or any event mentioned in VHA Handbook 1058.01, Research Compliance Reporting Requirements. The R&DC expects that the committee of record will have reviewed the event and devised a corrective action plan, if necessary. The R&DC will review the subcommittee's recommendations for corrective action and may acknowledge the event and/or the subcommittee's determination and may also make additional suggestions to the committee of record or request additional information. Deliberations and/or suggestions will be documented in the R&DC's minutes and the PI will be notified as appropriate.

5L. Systemic Deficiencies

VA personnel, including WOC and IPA appointees, must ensure written notification of the VA facility's R&D Committee within 5 business days after becoming aware of any apparent systemic deficiency that has a reasonable likelihood of substantially compromising the facility's research protection programs, including persistent failure by any subcommittee of the R&D Committee to adhere to the requirements governing VA research.

The R&D Committee:

- Must review any notification of systemic deficiencies described above at its earliest practicable convened meeting, not to exceed 30 business days after the date of notification.

- May hold unscheduled meetings in response to emergent issues in accordance with VHA Directive 1200.01.

- Must determine whether the notification involves an actual systemic deficiency that could substantially compromise the VA facility's research protection programs, and if so:

- Must determine what remedial actions, if any, are warranted to ensure effective research protections;

- Must notify the VA Medical Facility Director and the ACOS/R&D within 5 business days after the determination; and

- The VA Medical Facility Director must report the determination and the resultant remedial actions to ORO within 5 business days after receiving the notification.

5M. Suspensions and Terminations

The R&DC shall notify the PI in writing of suspensions or terminations and shall include a statement of the reasons for the R&DC's actions. The terms and conditions of the suspension must be explicit. The investigator shall be provided with an opportunity to respond in person or in writing.

Where the R&DC Chairperson determines that such action is necessary to ensure the rights and welfare of animal or human subjects, the Chairperson may require an immediate, temporary suspension of enrollment of new subjects or of continued participation of previously enrolled subjects, pending review of the situation by the convened R&DC.

NOTE: *If protocol modifications are required by the R&DC, applicable subcommittees must review and approve the amendment prior to the amendment being initiated.*

6. R&D COMMITTEE MEMBERSHIP

The members of the R&DC are nominated by the R&DC and appointed by the MFD. Members and alternate members of the R&DC may be nominated by current R&DC members, subcommittee members, or members of the Durham VAHCS staff. All members must hold a VA paid appointment, WOC, or IPA.

The R&DC must consist of at least five voting members. Whenever possible, one member of the committee needs to have expertise in biostatistics and research design. If the facility has any Centers, such as Centers of Innovation, it is recommended, but not required, that at least one voting member of the R&DC be chosen from the Center. To the extent possible, the members should have diverse backgrounds with consideration as to race, gender, ethnicity, and expertise.

Members and alternate members are formally appointed by the MFD. The Durham R&DC has voting members that reflect the types of research conducted at the Durham VAMC. Alternate members must have comparable qualifications to those of the primary member. Members and alternates are listed on the R&D roster and in R&D minutes. The Research Program Administrator will maintain a 1) list of member appointment and expiration dates and 2) MFD appointment letters and will notify the ACOS/R&D of member term expirations.

Membership will meet the following requirements of VHA Directive 1200.01:

- At least two members from the Durham VAHCS staff who have major patient care or management responsibilities.

- At least two members who are VA investigators actively engaged in majorR&D programs or who can provide R&D expertise;

- A voting member may fill more than one criterion for required membership.

- Ex-officio members without a vote include the MFD, the COS, the ACOS/R&D, the AO/R&D, the Veterinary Medical Officer (VMO), and the Research Pharmacist. Other ex-officio members may be appointed to the Committee if their appointments assist the R&DC in fulfilling its responsibilities. The ACOS/R&D also functions as Executive Secretary of the Committee.

- Other individuals as consultants may be invited to assist the R&DC (see Section 6C.)

- Alternate members, like primary members, are formally appointed by the MFD and serve terms of 3 years. Each alternate member may substitute for one or more primary members, and each primary member may have one or more alternate. The roster must identify the primary member(s) for whom each alternate member(s) may substitute. The alternate member’s qualifications must be

comparable to those of the primary member to be replaced. The alternate member can only vote in the absence of the primary member.

6A. Voting Members Terms

Voting members are appointed by the MFD in writing and serve terms of 3 years. Members may be reappointed without any lapse in time if it is deemed in the Committee's best interest. The terms of members will be staggered to provide a partial change in membership annually.

6B. Election of a Chair

Committee members must elect a Chairperson every 1 or 2 years. The Chairperson must be approved and officially appointed, in writing, by the MFD. The Chairperson may be reappointed without any lapse in time. The Chairperson must not simultaneously chair a subcommittee of the R&DC. The Committee members may choose to elect a Vice-Chairperson (equivalently designated as Co-Chairperson). The Co-Chairperson must also be approved and officially appointed, in writing, by the MFD for a term of 1 to 2 years. The Co-Chairperson may be reappointed without any lapse in time and must assume the responsibilities of the Chairperson when the Chairperson is not available. The R&DC may also appoint a Chair Pro Tempore to serve when the chairperson(s) is/are absent and/or must be recused for a deliberation and vote.

6C. Use of Ad Hoc Expert Review (Consultant)

An expert ad hoc review member(s) or consultant may be requested to assist the R&DC if his/her subject matter expertise is required to provide adequate and appropriate review of the proposed research. Such expertise may be beyond, or in addition to, that available on the committee. Ad hoc reviewers may not be counted towards quorum and cannot vote.

6D. Training

Every 3 years the Chair and voting members of the R&D Committee are required to complete two modules from ORD and the Collaborative Institutional Training Initiative (CITI) on ethical principles of human research protection. Other information on training is available at https://www.research.va.gov/pride/training/optiosn.cfm and VHA Directive 1200.05(2).

Training is tracked and documented by the Research Office. Updated versions of the R&DC SOP and subcommittee SOPs are readily available to all members on the shared ("S:\") drive and/or hard copy.

The R&DC provides training guidelines for R&DC Membership (Appendix 3) for new members. In addition, the R&D Chairperson offers and recommends a face-to-face meeting with new members.

6E. R&DC Member Conflict of Interest

An R&DC member has a COI with a research study if s/he (or spouse or dependent child) has any significant financial interests in the study as defined by current VHA COI standards, or if s/he (or spouse or dependent child) is involved in the design, conduct, or reporting of the research.

An R&DC member must disclose the COI to the R&DC Chairperson and/or R&DC Administrator if the member has a perceived or actual COI with a research study to be reviewed. The R&DC member may not be the reviewer for a research project with which s/he has a COI. The research project will be reassigned and reviewed by an R&DC member that does not have a COI with the research to be reviewed.

The conflicted committee member may answer members' questions during the review process but must leave the room during discussion and vote on the study. The minutes for the meeting will show the member was recused from the vote and the member will not be counted in the quorum for the vote.

6F. Institutional Financial Conflict of Interest

An institutional financial COI may exist when:

- A Durham VAMC employee has disclosed an invention to the Department of Veterans Affairs (DVA), and/or
- The DVA has formally retained rights (issued a Determination of Rights letter) to the invention, and/or
- The Durham VAHCS has rights to royalties from a licensing arrangement for the invention, and/or
- The invention will be used in or will be the subject of research conducted at the Durham VAHCS.

Should any of those conditions exist, the R&DC will develop a plan to manage or eliminate the conflict or seek outside guidance. Such plans may include but are not limited to public disclosures of the institutional COI in publications, presentations, or other public announcements.

7. R&D COMMITTEE MEETINGS

The R&DC meets monthly on the fourth Wednesday at 12pm. Meetings may be rescheduled as necessary, for example, when quorum will not be achieved. Any number of special or interim meetings may be called by the Chair, R&DC. Special or interim meetings must adhere to quorum requirements.

7A. Agenda preparation and distribution

Investigators submit items for review to the Research Office. Research Office staff log items into the research tracking database and assign the submission to the R&DC when applicable. Meeting agendas for each committee are created based on this assignment. Research Office staff distribute agendas and materials for review to each committee one week prior to the scheduled R&DC meeting.

7B. Conduct of meetings

The R&DC conducts in-person meetings. If physical presence is not possible, a member may be considered present if participating through teleconferencing or videoconferencing. In that case the member must have received all pertinent material prior to the meeting and must be able to participate actively and equally in all discussions. Scheduled meetings may be cancelled and re-scheduled under special circumstance (e.g. lack of quorum, holiday, inclement weather, emergent issues, etc.). Unscheduled meetings will have the same quorum requirements as scheduled meetings. All official business must be conducted at convened meetings with quorum except for when allowed by designated review per VHA Directive 1200.01.

7C. R&DC Actions

R&DC actions on research proposals can be to:

- **Approve**. The research is approved with no changes (or no additional changes). The research may proceed.

- **Approve with Contingencies**. The contingencies may be minor being small in number and/or narrow in focus or major involving more than minor questions or concerns regarding the protocol, research plan, safety or other matters. The contingencies are so designated as minor or major by the committee at the time of the vote. The research may proceed after the required changes are verified, the protocol has been approved by the full committee (major) or designated review (minor) and all approval letters have been provided to the investigator.

- **Table or Defer**. Significant changes to the protocol are required or there is not enough information provided in the submission for the R&DC to make a determination. The R&DC determines that it lacks sufficient information about the research to proceed with its review andthat the changes are significant and/or so numerous as to require full committee re-review. The research may not proceed until the convened R&D Committee has approved a revised application incorporating all stipulations.

- **Disapprove**. The research, as proposed, cannot be approved and initiated at Durham VAHCS due to serious scientific or ethical concerns.

7D. Quorum

All voting items presented to a convened meeting requires quorum consisting of a majority of voting members of the Durham VAHCS R&DC. Quorum can be lost if a member or members left a meeting early or recused themselves due to conflicts of interest. In such circumstances affected item(s) for review would be deferred until either 1) a quorum was re-established, 2) items were reviewed at a specially-convened meeting, or (3) postponed until the next regularly-scheduled meeting. The Research Program Assistant is responsible for monitoring the quorum during R&D meetings. Should the Research Program Assistant not be present this duty may fall to the Chair or any ex officio non-voting member.

7E. Voting

All R&DC actions (approvals, contingent approvals, tabling/deferring, and disapprovals) must be by a majority vote of the convened quorum. Each voting member has one vote. No proxy votes (written or telephone) are allowed. Types of votes include:

For. Present at the convened meeting, participates in final deliberations and votes for approval/motion.

Against. Present at the convened meeting, participates in final deliberations and votes for disapproval/motion.

Abstained. Present at the convened meeting, participates in final deliberations and chooses not to vote. Members who abstain are counted toward the quorum.

Recused. Present at the convened meeting, declares a conflict of interest, leaves the room, does not participate in final deliberations and does not vote. Recused members are not counted towards the quorum.
Excused. Present at the convened meeting however has left the room for personal reasons during final deliberations and does not vote. Excused members are not counted towards the quorum.

In instances where the R&DC is being informed of an item or event, the R&DC may acknowledge the item or event without taking a vote. Such instances include but are not limited to: (1) old business items, (2) new business items, (3) notifications, and (4) compliance reviews.

8. R&D COMMITTEE RECORDS

Required R&DC records include, but are not limited to, (1) minutes of the R&DC and R&DC subcommittees, (2) copies of all written correspondence, and (3) membership lists for the R&DC and all R&DC subcommittees.

8A. R&DC Minutes

In general, minutes shall include items discussed, any modifications required, all actions taken by the convened R&DC and the votes underlying those actions. Minutes must document the approval of prior R&DC or subcommittee minutes, and discussions regarding all items of business or information brought before the R&DC.

Minutes are recorded and include names of all voting members and non-voting members (including ex-officio members), indicating the category of their membership and whether the member was present or absent. If an alternate member is present in place of a voting member, the minutes must indicate this fact and name who the alternate member is replacing.

Minutes document the presence of a quorum and types of actions taken by the R&DC, the vote on the action, including the number voting for, against, and abstaining. Excused members must be listed by name. Recused members from the vote must be named and it must be documented whether or not the member was present during the discussion.

Minutes document summaries of discussions (including controverted issues) and any decisions made as a result of the discussion; the basis for requiring changes to a research project, program, or center in order to obtain approval; any required follow-up including which committee, subcommittee, or person is responsible for the follow-up; and the basis for disapproving a research project, program, or center when this occurs. Minutes will also include the stipulations required for research projects that have been contingently approved, tabled or disapproved. For contingent approvals, minutes will document that stipulations were met and that final approval has been granted.

Draft minutes from the previous R&DC meeting are provided to R&DC members with the next meeting agenda packet. The convened R&DC will review the minutes from their previous meeting and vote to approve or disapprove. If any R&DC member has questions or concerns with the draft R&DC minutes, revisions will be made and presented for review and approval at the next R&DC meeting. R&DC minutes are filed with the Research Service. All minutes of the R&DC are sent to the MFD through the ACOS/R&D and COS for review and appropriate action.

Protocols receiving final approval by designated review must be presented to the R&DC as agenda items at the next convened meeting and noted in that meeting’s minutes.

8B. Subcommittee Minutes

Draft minutes from the most recent subcommittee meetings are distributed to all R&DC members prior to the next R&DC meeting so that draft minutes may be used to aide reviewers in their deliberations, if applicable.

Final subcommittee minutes (e.g., minutes that have been approved by the subcommittee) are also distributed to the R&DC with the agenda packet. During the

convened R&DC meeting, members review and vote to approve or disapprove the final subcommittee minutes. If the R&DC has questions or concerns about a subcommittee's final minutes, comments will be relayed back to the subcommittee.

8C. Research Proposal Records

Each research proposal is given a separate file. Protocols are assigned a unique number in the research tracking database and a unique grant number from the electronic Project Management and Information System (ePROMISE) for tracking and administrative purposes. The research tracking database stores information regarding each document received, when it was reviewed, and the results of that review. Additionally, the research tracking database tracks changes that are needed, when those changes were received and approved, and the date of continuing review. The research tracking database also tracks R&DC membership and generates meeting minutes and correspondence regarding Committee actions to principal investigators. Research Service also enters data into the ePROMISE Database system that is provided by VA Central Office to track research projects.

Copies of all research proposals, amendments reviewed, and all other submitted and reviewed material, compliance reports, all continuing and final reports, R&DC and Subcommittee minutes, copies of all written correspondence, membership rosters for the R&DC and all Subcommittees, are stored in secure locations. The records of VA-approved research studies conducted at Durham VAHCS are stored in locked secure areas in the Research Office of the Durham VAHCS and archived accordance with National Archives and Records Administration (NARA) regulations at the NARA facility in Neosho, Missouri. Research Service maintains all records collected over the course of a study. All records are accessible for inspection and copying by representatives of VA, sponsors, other Federal regulatory agencies or others with written authorization at reasonable times and in a reasonable manner.

Records are maintained in locked Research Office space. Access to records is limited to the ACOS/R&D, AO, Committee and Subcommittee members, Research Compliance Officers (RCOs), Research Administrative Office staff, authorized VA representatives, officials of Federal and State regulatory agencies, including but not limited to the Office of Research Oversight (ORO), the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA). Research investigators shall be provided reasonable access to files related to their research in the presence of a Research Office staff person. Appropriate accreditation bodies, such as AAALAC International, etc., shall be provided access to research records.

Research records may be electronic or paper. When original signatures are required on documents, either a paper copy of the signature sheet must be maintained or an electronic signature may be used. If an electronic signature is used, it must meet all requirements of VA, OHRP, FDA, and any other Federal requirements.

8D. Correspondence with Investigators

The PI is notified in writing of the R&DC's decision to approve, approve with conditions, disapprove a proposed research activity, or if modifications are required to secure R&D approval. The PI is notified in writing of the results of the R&DC's continuing review of the project. If the R&DC disapproves or requires modifications of proposed research to obtain approval, and the disapproval or modification affects a committee or subcommittee review, the appropriate committees or subcommittees (e.g., IACUC, IRB, and SRS), must be notified in writing and reconsider the proposal.

Signed copies of the correspondence will be provided to investigators for their files. Responses to the R&D Committee should come from the PI or a designated study coordinator and must be signed by the PI.

9. SUBCOMMITTEES OF THE R&D COMMITTEE

The R&DC may establish any subcommittees deemed necessary for the efficient and effective management and oversight of the R&D Program. The Durham VAHCS has established the following R&DC subcommittees:

- Institutional Review Board (IRB)
- Institutional Animal Care and Use Committee (IACUC)
- Subcommittee on Research Safety/Institutional Biosafety Committee (SRS/IBC)

Each subcommittee records minutes of its meetings and reports to the R&DC, who approves or disapproves its findings or requires modifications in order to secure approval, except that the R&DC cannot approve a study that is disapproved by a subcommittee but the R&DC may disapprove a study approved by a subcommittee. The R&DC may request that a subcommittee re-review an action if R&D feels that new information needs to be considered. Changes resulting from R&DC review affecting human, animal, safety, or space issues are referred to the appropriate subcommittee for further review and/or consideration.

9A. Institutional Review Board (IRB)

The R&DC has charged the Durham VAHCS Institutional Review Board (IRB) with the scientific and ethical review and oversight of all research activities involving the use of human subjects. This includes the responsibility of maintaining the assurances of compliance set forth in the Federal Wide Assurance and according to the standards set by the accrediting organization under contract with the VHA. The R&D Committee oversees the IRB in this responsibility.

An annual quality assurance review of the IRB is conducted. This review consists of IRB composition, report of credentialing and training, space, support staff, quality improvement activities, compliance issues, and goals for the next year.

9B. Institutional Animal Care and Use Committee (IACUC)

The R&DC has charged the Durham VAHCS Institutional Animal Care and Use Committee (IACUC) with the scientific and ethical review and oversight of all research activities involving the use of animals in research. This includes the responsibility of maintaining an Animal Welfare Assurance set forth in the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals. The R&D oversees the IACUC in this responsibility.

An annual review of the Animal Care and Use Program, including the IACUC, is conducted and includes inspection reports, IACUC composition, IACUC arrangements, space, support staff, training, quality improvement activities, compliance issues, and goals for the next year.

9C. Subcommittee on Research Safety/Institutional Biosafety Committee (SRS/IBC)

The R&D Committee has charged the Durham VAHCS Subcommittee on Research Safety (SRS/IBC) with the review and oversight of research proposals involving biological, chemical, physical, radiation hazards, and recombinant DNA for compliance with all applicable regulations and policies. This includes a review of all research applications for funding that will be conducted at the VA facility or by VA personnel with VA funding located off-site. The SRS/IBC assesses the impact of each agent on the safety of personnel working in research laboratories. All research projects involving biological, chemical, physical, radiation hazards, and recombinant DNA must be approved by SRS and then by the R&D Committee prior to commencement.

An annual review of the Research Safety and Security Program and SRS/IBC is conducted and includes planned training, compliance, and security issues.

9D. R&DC External Committees

External committees of the Durham VAHCS R&DC include the VHA Central Institutional Review Board (CIRB), the National Cancer Institute Institutional Review Boards #1 (Adult, Late Phase Emphasis), #3 (Adult, Early Phase Emphasis), and #4 (Cancer and Prevention Control). The R&DC will review on an annual basis the MOUs established with these IRBs and any other IRBs that are established as an external committee.

10. INVESTIGATOR RESPONSIBILITIES

The Principal Investigator (PI) assumes ultimate responsibility for the conduct of research

according to federal, sponsor and organizational guidelines and attests that adequate resources are available to conduct the study. The investigator may delegate research duties but is ultimately responsible for all aspects of their research program and protocol(s). Investigators are required to complete annual research training and to provide adequate documentation of training to the Research Office. The PI is responsible for training and oversight of his/her research staff. The investigator assumes responsibility for his/her research subjects and employees and is available to answer questions. Investigators are authorized to have access to the VA shared drive where research policies, submission forms and SOPs are posted and available.

The Durham R&DC recognizes one PI for each project. Physician PIs who engage in clinical activity as part of a research protocol that requires clinical privileges (and others as required by VA regulations) must be credentialed and privileged at Durham VAHCS. All PIs and research staff must have VA paid employee status, WOC status, or be appointed or detailed to VA under the Inter-governmental Personnel Act (IPA) of 1970 and have provisions for appropriate space at the VA prior to initiating research activities. Contractors can provide clinical services or other activities in support of VA research in accordance with their contract. Non-licensed physicians cannot practice medicine; authorized research duties are described in a Research Scope of Practice. The PI has ultimate responsibility for his/her research project and all official R&DC and Subcommittee correspondence is addressed to the PI. Trainees, as defined in VHA Directive 1200.02, cannot serve as a PI but may conduct research at a VA medical facility and serve as a co- or sub-investigator, use VA data, or use human biological specimens that have been collected within VA for clinical, administrative, or research purposes. Trainees must work under a PI sufficiently experienced in the trainee's research interest area(s) to serve as the PI. Durham VAHCS research personnel may only perform duties according to their licensure, education, training, experience, job description, Research Scope of Practice, VHA credentialing and privileging, and Human Resources policies, as applicable.

Investigators are responsible for:

- Holding specific credentials and privileges awarded by the VA facility and VHA (when applicable) to conduct research in VA. Investigators must be qualified through education and experience.

- Complying with all applicable VHA policies.

- Obtaining the complete approval of all appropriate non-research entities and R&D Committee subcommittees, and written notification from the ACOS/R&D prior to initiating a research project.

- Developing a research plan that is scientifically valid; minimizes risk to human subjects and animals used in research, and to personnel. The research plan includes a sufficient description of the research including procedures and analysis plans to allow the R&DC (and other committees) to fully review the research project.

- Submitting and implementing plans for data use, storage, and security to the Privacy Officer(s) and Information System Security Officer(s) that are consistent with VHA Directive 1605.01, VA Directive 6500 and other relevant Federal statutes, regulations, and policies.

- Preparing and submitting information at least annually or as otherwise required on their research project(s) to the R&DC or the appropriate subcommittee for continuing review.

- Ensuring that all research proposals submitted for funding, from any source, support the mission of VHA and enhance the quality of health care delivery to Veterans.
- Following ORD's current guidelines for submitting publications or presentations of original research, commentaries, review articles, letters to the editor, andother journal publications to ORD's PubTracker prior to publication or presentation.

- Submitting a completed, signed, and dated OGE Form 450 Alternative – VA Research Financial Conflict of Interest Statement for review by the Conflict of Interest Committee prior to: (1) initial review of a protocol when the individual is listed as an Investigator, (2) continuing review of a protocol when the individual is listed as an Investigator, (3) being added as an Investigator to an existing protocol, and (4) a change in relevant information requires a change in conflict of interest reporting.

Appendix 1: Training Guidelines for R&DC Membership

1. Primary responsibility: The R&DC is responsible for oversight of the research program and for maintaining high standards throughout the R&D Program. The R&DC reports through the COS to the MFD. The R&DC assisted by the ACOS and Administrative Officer of R&D to collectively ensure the:
   a) scientific and ethical quality of VA research projects,
   b) protection of human subjects in research,
   c) safety of personnel engaged in research,
   d) welfare of laboratory animals,
   e) security of VA data, and
   f) security of VHA research laboratories.

Research at the facility may not be undertaken without R&DC and appropriate subcommittee approval.

2. Review R&D Committee Handbook (1200.01 dated June 16, 2009)

3. Administrative Duties
   a) Planning and developing broad objectives for R&D program.
   b) Determining the extent to which R&D has met it objectives.
   c) Reviewing budgetary and other resource needs, at least annually and making appropriate recommendations regarding these needs (e.g., personnel, materials, supplies, space, capital equipment, training, and education).
   d) Assuring compliance with all personnel policies.
   e) Annual quality assurance review of all subcommittees and other key components of R&D functions.

4. Review of Research: The R&DC is responsible for reviewing research that is otherwise not reviewed by the IRB or IACUC for scientific quality and appropriateness to promote the maintenance of high scientific standards, the protection of human subjects including privacy and confidentiality, the welfare and appropriate use of animals for research, the safety of personnel involved in research, the security of research laboratories, the security of VA data protected and sensitive information, the availability of adequate resources to conduct and complete the research, and the relevance of research to support the VA mission. Each research project otherwise not reviewed by the IRB or IACUC must be reviewed and approved initially and at least annually thereafter.

   Initial Reviews: In conducting an initial review of otherwise projects not reviewed by the Durham IRB or IACUC, the R&DC must evaluate the scientific quality, relevance, and ability of the investigator to perform and complete the research. The review must include information on the use, storage, and security of VA data and sensitive information, budget, requirements for space, personnel, equipment, and supplies, the role of the investigator at the facility, the investigators qualifications, and any subcommittee findings. The R&DC also reviews studies approved by the CIRB, the creation and operation of research data repositories, and individual protocols that will use data from a research or non-research data repository

   Continuing Reviews: The continuing review of CIRB studies, research data repositories, protocols that use data from a data repository, and projects otherwise not reviewed by

the Durham IRB or IACUC must assess the research activities that have occurred, the progress of the research, and any issue that may impact the progress of the research including compliance issues. The review must include an assessment of data security, confidentiality of data, release of data, and control of the data so that reuse of the data is within an approved research protocol and in compliance with VHA procedures. The review must include a quality assurance review of publications assessing the acknowledgement of VA support and affiliation.

5. R&DC Meetings: The R&DC meets monthly (4th Wednesday of every month at noon). Review agenda carefully for study assignments.
    a. Scientific Reviews
        i. Minutes from previous meetings are reviewed and voted on.
        ii. Continuing reviews are divided between two committee members for review.
        iii. Contingent reviews are reassigned if possible to the persons who requested a contingency for review to determine if contingencies have been met.
        iv. . . Initial reviews are divided by expertise among the committee members not involved in the continuing reviews. This must be the most thorough and comprehensive review of all reviews (see above for guidelines).
    b. Business Items
        i. Monthly combined executive subcommittee reports reviewed
        ii. Monthly business report from the AO
        iii. Old Business items discussed as needed
        iv. New business items discussed as needed

If a member is unable to attend a specified meeting, the research office should be contacted in advance so that scientific reviews can be appropriately assigned. Once assigned, if unable to attend a meeting, written review of the assigned project(s) should be sent to the research office, R&D chair, and the second reviewer of the assigned protocol(s).

Appendix 2: R&DC Reviewer Checklist

PI: Date:

Project Title:

	YES	NO	N/A	COMMENTS
1) Is the scientific design described?	☐	☐	☐	
2) Is the scientific design adequately justified?	☐	☐	☐	
3) Is the scientific design adequate to answer the questions(s)?	☐	☐	☐	
4) Are the aims/objectives likely to be achievable within the given time period?	☐	☐	☐	
5) Is the statistical analysis plan appropriate?	☐	☐	☐	
6) Is the safety monitoring plan appropriate for human studies? (e.g., Is there a need for a DSMB/Data Monitoring Committee if one does not exist?)	☐	☐	☐	
7) Was there a thorough evaluation of relevant literature and previous studies?	☐	☐	☐	
8) Is the investigator qualified by education/training to conduct the study?	☐	☐	☐	
9) Does the investigator have adequate resources (i.e., staff, space) to conduct the project?	☐	☐	☐	
10) Has a Conflict of Interest been identified? a) If yes, has the COI been adequately managed?	☐ ☐	☐ ☐	☐ ☐	
11) Does the protocol involving the collection, use and/or storage of research information including subject identifiers and PHI contain specific information on all sites where the data will be used or stored, how the data will be transmitted or transported, who will have access to the data, and how the data will be secured?	☐	☐	☐	
12) Is the research relevant to Veterans or active duty military personnel?	☐	☐	☐	

PI: Date:

Project Title:

13) Will non-Veterans be recruited and/or enrolled in the research?	☐	☐	☐	
Additional Recommendation(s):				
Signature of Reviewer/Date of Review:				